

**REMARKS****Status of the Claims**

Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 were previously submitted for examination, and were rejected. Claims 23 and 47 have been canceled. Claims 18, 22, 34, 44 and 46 have been amended to clarify the meaning of the claims. No new matter has been introduced by way of these amendments. Upon entry of the current amendment, claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48 and 50-52 will be pending. Entry of the amendments and consideration on the merits is respectfully requested.

With respect to all amended and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

**Claim Objection**

Claim 18 was objected to because of the redundant recitations of “prepared by extrusion”. Applicants have amended claim 18 to delete one of recitations. Accordingly, this objection may now be withdrawn.

**Claim Rejection under 35 U.S.C. § 112, Second Paragraph**

Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention, because claims 18-19 (and all the claims depending therefrom) were found to be indefinite in the recitation of the term “increased pelleting stability”. First, the Examiner alleged that the term is “unclear and confusing in the absence of a basis for comparison (i.e., increased with respect to what)” (the OA at p. 3, ¶ 4). The

Examiner further alleged that a person skilled in the art at the time of the invention “would interpret the term ‘pelleting stability’ to refer to the structural stability of the pellet under different conditions (e.g., temperature, pressure, pH, etc.)” (Id.) Since the Examiner could not determine the intended meaning of the term “pelleting stability,” no patentable weight was given to the term and correction or clarification of the term was requested. Applicants respectfully traverse this rejection for the reasons set forth below.

Patent claims must “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, paragraph 2 (1982). “A determination of claim indefiniteness is a legal conclusion that is drawn from the court’s performance of its duty as the construer of patent claims.” *Personalized Media Communications, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 705 (Fed. Cir. 1998). The perspective of a person of ordinary skill in the art at the time of the patent application governs the indefiniteness analysis. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556-57 (Fed. Cir. 1983). The definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claims when read in light of the specification. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986)). “A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular [product or method] infringes or not.” *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

Applicants respectfully submit that a person skilled in the art would have understood the bounds of the claims when read in light of the specification and the knowledge available in the art at the time of the invention. The Expert Declaration under 37 C.F.R. § 1.132, signed by Dr. Lutz End (**Exhibit A**), discusses how a skilled artisan, using the specification and teachings within, and the knowledge of one skilled in the art, would have interpreted the meaning of “increased pelleting stability” at the time of the invention.

**The following paragraphs (3-20) are taken directly from the § 1.132 Expert Declaration of Dr. Lutz End, Head of Formulation and Nutrition R&D in the Care Chemicals Division at BASF SE (formerly known as the Fine Chemicals Division of BASF Aktiengesellschaft).**

3. I hereby declare that the skilled artisan, at the time of the invention, using the teachings of the specification and the knowledge known to the skilled artisan, would have understood that the term “pelleting stability” was intended to refer to residual phytase activity in the pellet after the pelleting process, and not to the structural stability of the pellet itself.

4. To illustrate the state of the art at the time of the invention, the Examiner is first referred to the text of the instant specification as published (US 2002/0034798 A1), specifically to Example 5 entitled “High Activity Phytase Stability Tests” on pages 7-8 (paras. [0114] – [0127]).

5. The preamble of Example 5 clearly states that “[t]o demonstrate that a higher enzyme concentration (in granules made using the high activity phytase liquid) gives a higher pelleting stability, granulates with an increasing enzyme concentration were made and the pelleting stability of these samples were tested” (para. [0115]).

6. The descriptions of Comparative Samples A, B, C indicate that the three enzyme granulates had pre-pelleting phytase activities of 610 FTU/g, 4170 FTU/g and 6830 FTU/g, respectively (see paras. [0116] - [0124]).

7. The final section of Example 5 is entitled “Comparison of pelleting stabilities.” The section states that the enzyme granulates A, B and C were mixed with a feed premix at different mixing ratios, pre-treated by steam injection to give a temperature rise to 75°C, after which the mixtures were pelleted in a pelleting machine to obtain the feed pellets at a temperature of 82°C, which were subsequently dried. The section further explains that this process is typical for the feed industry to obtain feed pellets (see para. [0126]).

8. After the pellets were dried, the enzyme activity was measured again (data not shown), and the post-pelleting yield was calculated by comparing the residual phytase activity of each sample with corresponding pre-pelleting activity adjusted for the different mixing ratios with the feed premix. The resulting post pelleting phytase activity yields are summarized in Table 2, which shows that the low-phytase Comparative Sample A had a less than 17% yield, whereas the high-phytase Comparative Samples B and C had significantly higher yields of 37% and 48%, respectively. Accordingly, Applicants conclude that “the two granules with the highest enzyme concentration had much higher pelleting stability” (para. [0127]).

9. It is important to note that structural stability of the pellets is not discussed at all in Example 5, whereas all of the discussion focuses exclusively on phytase activity. Therefore, the only reasonable conclusion that could have been made by a skilled artisan at the time of the invention is that the higher pelleting stability contemplated by the present invention means a higher yield of residual phytase activity after pelleting, and not higher structural stability of the pellets.

10. To further illustrate the state of the art at the time of the invention, the Examiner is next referred to several prior art references discussing issues relating to pelleting stability.

11. The problem of post-pelleting phytase performance was recognized as early as 1990, when Simons wrote:

“The pelleting experiments with feed to which microbial phytase had been added showed significant inactivation of phytase activity when temperatures of the pellets after pelleting exceeded 84° C...” P.C.M. Simons, et al., Improvement of Phosphorus Availability by Microbial Phytase in Broilers and Pigs, *Br. J. Nutr.* 1990, 64:525-540, at p.537 (**Exhibit B**).

12. In 1993, Cowan referred to enzyme stability in the context of feed pelleting:

“At a pre-pelleting conditioning temperature of 65° C, a commercial enzyme absorbed to its carrier is completely *stable*. However, as the conditioning temperature increases, the enzyme is inactivated until at 75° C the residual activity is about 30%

of the starting level.” W.D. Cowan, The Stability of Enzymes in Animal Feeds, *Feed Intl.* 1993, 14(4):22-25, at p. 23 (**Exhibit C**).

13. In the same year, Gadiant also remarked that:

“hydrothermal processes, such as pelleting, extrusion and expansion, have been recognized as potentially destructive for... phytase.” M. Gadiant, et al., Experiences with Enzymes in Feed Manufacturing, in *Proc. 1<sup>st</sup> Symp. on Enzymes in Animal Nutrition*, Kartause Ittingen, Switzerland, Oct. 13-16, 1993, 255-262, at p. 255 (**Exhibit D**).

14. Similarly, in 1993 Nunes wrote:

“The resistance of endogenous phytase and eventually that of the added one to the pelleting temperature appeared as an important question... It appeared that steam-pelleting at temperatures higher than 60° C strongly reduced phytase activity. This was particularly marked for temperatures higher than 75° C. When pelleting at 80° C the recovered phytase activity represented about 50% of the endogenous one demonstrating inactivation of both enzymatic activities... Thus, with the aim of phytase preservation in pig feed technological precautions should be taken when using steam-pelleting.” C.S. Nunes, Evaluation of Phytase Resistance in Swine Diets to Different Pelleting Temperatures, in *Proc. 1<sup>st</sup> Symp. on Enzymes in Animal Nutrition*, Kartause Ittingen, Switzerland, Oct. 13-16, 1993, 269-271 (**Exhibit E**).

15. Consistent with the earlier reports, in 1995 Ravindran noted:

“High temperatures employed during ingredient processing or during pelleting of diets can also influence the native phytase activity of plant ingredients. Plant phytase activity is not altered by such treatments at temperatures between 47° and 62° C, but higher temperatures (70-80° C) can cause partial or total inactivation.” V. Ravindran, et al., Phytates: Occurrence, Bioavailability and Implications in Poultry Nutrition, *Poult. Avian Biol. Rev.* 1995, 6(2):125-143, at p. 129 (**Exhibit F**).

16. In 1997, Spring used the term “stability curve” in the context of feed pelleting:

“Enzymes are susceptible to hydrothermal treatments as applied in pelleting, expansion and extrusion. It appears that each enzyme product has a specific ‘*stability curve*’ and a critical temperature point at which enzyme losses start to accelerate.”

W.G. Spring, et al., Application of Enzymes in Compound Feeds, *CIHEAM – Options Mediterraneennes* 1997, 26:175-179, at p. 176 (**Exhibit G**).

17. In 1997, Esteve-Garcia also wrote about enzyme stability during pelleting:

“Stability of enzymes during the pelleting process has been a cause for concern.” E. Esteve-Garcia, et al., Bioefficacy of Enzyme Preparations Containing  $\beta$ -Glucanase and Xylanase Activities in Broiler Diets Based on Barley or Wheat, in Combination with Flavomycin, *Poult. Sci.* 1997, 76:1728-1737, at p. 1728 (**Exhibit H**).

18. Finally, in 1998, the year of the present invention, Wyss specifically used the term “pelleting stability”:

“Enzymes that are used in animal feed supplements should be able to withstand temperatures of 60° to 90° C, which may be reached during the feed pelleting process... These findings confirm that *A. niger* pH 2.5 acid phosphatase is irreversibly inactivated at temperatures above 80° C and that the capacity of *A. fumigatus* phytase to refold properly after heat denaturation may favorably affect its pelleting stability.” M. Wyss, et al., Comparison of the Thermostability Properties of Three Acid Phosphatases from Molds: *Aspergillus fumigatus* Phytase, *A. niger* Phytase, and *A. niger* pH 2.5 Acid Phosphatase, *Appl. Envir. Microbiol.* 1998, 64(11):4446-4451, at p. 4446, abstract; see also p. 4450 (**Exhibit I**).

19. Thus, based on the prior art literature, there is a clear sense that each enzyme has its own pattern of thermal inactivation as a result of feed pelleting, also known as a “stability curve”. Any modifications to the enzyme itself and/or to the process of granulation that have a tendency to shift the stability curve to the right, i.e., toward a higher temperature tolerance, would be understood by a skilled artisan to result in an “increased pelleting stability” as recited in claims 18 and 19 of the present application.

20. Accordingly, based on the teachings of the specification and the knowledge and methods known at the time of the invention, the skilled artisan would have appreciated that the term “increased pelleting stability” was intended to refer to a higher than normal post-pelleting phytase activity in the pellet, and not to the structural stability of the pellet itself.

It is also important to note that the Board of Patent Appeals and Interferences has recently decided an appeal (Appeal No. 2006-0201) in a related pending application (Appl. No. 10/125,272), wherein the Board had no difficulty interpreting the meaning of “pelleting stability” in a manner consistent with the discussion above: “The specification reports that coating the granules with polyethylene glycol (PEG)... ‘provide[s] a good pelleting stability of the granule,’ i.e., results in less loss of enzyme activity during pelleting” (**Exhibit J**, page 2, third paragraph).

In light of the foregoing arguments, Applicants respectfully submit the indefiniteness rejection of claims 18-19, and all the claims depending therefrom, under 35 U.S.C. § 112, second paragraph should be withdrawn, and that the term “increased pelleting stability” given patentable weight in any future consideration of the pending claims.

#### **Claim Rejections under 35 U.S.C. § 103**

Claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48 and 50-52 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).

Claims 22-23 and 46-47 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48 and 50-52 above, and further in view of Markussen et al. (US Patent No. 4106991, 1978).

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-45, 48 and 50-52 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996), and further in view of Haarasilta (GB 2-139868A, 1984).

Claims 23 and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811,

filed 10/4/1996) and Haarasilta (GB 2-139868A, 1984) as applied to claims 22 and 46, and further in view of Markussen et al. (US Patent No. 4106991, 1978).

All these rejections were maintained for the reasons of record in view of the fact that the limitation “high activity phytase-containing granulate” recited in claims 18-19 had not been given patentable weight because the claims already recited how much phytase activity was required in the granulate (i.e., at least 6000 FTU/g), and the limitation “increased pelleting stability” had not been given patentable weight for the reasons discussed above. Applicants respectfully traverse these rejections for the reasons of record in view of the current claim amendments, the foregoing arguments in favor of giving the limitation “increased pelleting stability” patentable weight, and for additional reasons set forth below.

The Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* at 1532. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). A *prima facie* case of obviousness requires the satisfaction of three requirements. First, the combined prior art references must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); MPEP § 2143.03. Second, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference to achieve the claimed invention. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007). And third, there must be a reasonable expectation of success found in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2143.02.

The Examiner has acknowledged that (1) neither Nielsen, Ghani, Markussen, nor Haarasilta discusses pelleting stability with regard to phytase granulates, and (2) Nielsen does not teach extrusion as the method for making the granulate (the OA at p. 6, ¶ 14). With regard to pelleting stability, as discussed previously, the limitation was not given patentable weight under 35 U.S.C. § 112, second paragraph. The Examiner further noted that, even if the term were to be given



patentable weight, “this additional limitation would be considered inherent to a phytase granulate having at least 6000 FTU/gram.” (Id., emphasis added). Thus, the Examiner’s entire argument is based on inherency, namely the increased pelleting stability of any phytase granulate having at least 6000 FT/gram. Applicants respectfully submit that this rejection under 35 U.S.C. § 103(a) was based on an erroneous application of the inherency principles.

The source of law for inherency in the context of obviousness rejections may be found in MPEP § 2141.02.V, which states: “Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.” *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Applicants respectfully submit that *In re Rijckaert* is not merely an outlier case. There is a significant body of case law going back over forty years that stand for essentially the same proposition that “the inherency of an advantage and its obviousness are entirely different questions[;] [t]hat which may be inherent is not necessarily known[;] [o]bviousness cannot be predicated on what is unknown.” *In re Spormann*, 363 F.2d 444, 448; 150 USPQ 449 (CCPA 1966).

Aside from *In re Rijckaert*, Applicant identified a number of obviousness cases, all of which are still good law, that have followed the general legal principle stated in *In re Spormann* (see, e.g., *In re Newell*, 891 F.2d 899; 13 USPQ2d 1248 (Fed. Cir. 1989); *Application of Shetty*, 566 F.2d 81; 195 USPQ 753 (CCPA 1977); *In re Rinehart*, 531 F.2d 1048; 189 USPQ 143 (CCPA 1976); *In re Naylor*, 369 F.2d 765; 152 USPQ 106 (CCPA 1966). These cases unequivocally suggest that, while inherency may be used to “fill the gaps” to satisfy the “all elements” prong of *prima facie* obviousness under 35 U.S.C. § 103(a), inherency may not properly serve as a substitute for a teaching, suggestion or motivation to modify or combine, or for a reasonable expectation of success. Here are a few examples of pertinent language for the sake of illustration:

“[A] retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination.” *In re Newell* at 901 (citing *Smithkline Diagnostics v. Helena Labs Corp.*, 859 F.2d 878, 886-87, 8 USPQ2d 1468, 1475 (Fed. Cir. 1988)(emphasis added).

“The Patent Office has failed to show a reasonable expectation, or some predictability, that Brake’s compound would be an effective appetite suppressant if administered in the dosage disclosed by Narayanan. The mere hindsight assertion that corresponding dosages render appellant’s method obvious is untenable.” *Application of Shetty* at 86 (emphasis added).

“The tribunals below did not meet the requirement of establishing some predictability or success in any attempt to combine elements of the reference processes in a commercial scale operation... The view that success would have been ‘inherent’ cannot, in this case, substitute for a showing of reasonable expectation of success.” *In re Rinehart* at 1053-54 (emphasis added).

[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result... [W]e find nothing in the record which would afford one of ordinary skill reason to anticipate that a trial of the Badische-Anilin ‘promoters’ in the Crawford process would be successful in producing the polymer recited in the claims.” *In re Naylor* at 768 (emphasis added).

In light of the foregoing legal discussion, Applicants respectfully submit that, in this case, the Examiner has failed to establish either the suggestion or motivation prong, or the reasonable expectation of success prong of *prima facie* obviousness.

As the Examiner has already acknowledged, neither Nielsen, Ghani, Markussen, nor Haarasilta discusses pelleting stability with regard to phytase granulates. Under the holdings of *In re Newell* and *In re Rijckaert*, the Examiner may not properly use inherency as a retrospective substitute for some teaching, suggestion or motivation to combine references. Accordingly, Applicants respectfully submit that there was no adequate suggestion or motivation found in the cited references or any other prior art or to combine the cited references in order to practice the presently claimed invention.

With respect to the reasonable expectation of success prong of the *prima facie* standard of obviousness, the Examiner’s entire argument is predicated on the now-established increased pelleting stability of high activity phytase granulates. In light of the foregoing discussion, Applicants respectfully reiterate that a reasonable expectation of success is an objective test that is

always applied at the time the invention was made, and cannot be employed retrospectively. Under the holdings of *In re Rinehart* and *In re Naylor*, the view that success would have been inherent cannot substitute for a showing of reasonable expectation of success. Since it was not known at the time of the present invention that high activity phytase granulates had increased pelleting stability, a skilled artisan could not have reasonably expected to succeed by combining the teachings of Nielsen with those of Ghani, Markussen and/or Haarasilta.

Thus, at least since there is no adequate suggestion or motivation to combine the references, and no reasonable expectation of success due to the combination of the teachings of Nielsen with those of Ghani, Markussen and/or Haarasilta, a *prima facie* case of obviousness has not been made, and therefore the rejections under 35 U.S.C. § 103(a) may be properly withdrawn.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 251502008600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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